NEWS RELEASE

Merck’s Tulisokibart Met Primary and Key Secondary Endpoints in the Phase 3 ATLAS-UC Induction-only Study in Patients With Moderately to Severely Active Ulcerative Colitis (UC)

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Tulisokibart is the first anti-TL1A monoclonal antibody to demonstrate clinical remission at 12 weeks in moderately to severely active UC in a Phase 3 trial

Tulisokibart was designed to help address immuno-fibrosis, a key driver of disease progression in inflammatory bowel disease (IBD) and other immune-mediated inflammatory conditions

RAHWAY, N.J.--(BUSINESS WIRE)-- Merck (NYSE: MRK), known as MSD outside of the United States and Canada, today announced positive topline results from the Phase 3 ATLAS-UC induction-only study (Study 2) evaluating tulisokibart (MK-7240), an investigational humanized monoclonal antibody targeting tumor necrosis factor-like cytokine 1A (TL1A), in patients with moderately to severely active UC. The study successfully met its primary endpoint of clinical remission according to the Modified Mayo Score (MMS) at week 12, as well as key secondary endpoints. Consistent with previously reported Phase 2 studies, no safety concerns were identified.

“These positive Phase 3 induction results for tulisokibart are the first for an anti-TL1A biologic. They represent an important step forward for patients with moderately to severely active ulcerative colitis who – despite available treatments – continue to experience symptoms, and do not achieve clinical remission,” said Dr. Eliav Barr, senior vice president, head of global clinical development and chief medical officer, Merck Research Laboratories. “These results reinforce the potential of this novel approach designed to help address immuno-fibrosis, a key driver of

chronic immune dysregulation and disease progression in ulcerative colitis."

Results from the ATLAS-UC Study 2 will be presented with the results from the ongoing induction and maintenance study (Study 1) at an upcoming scientific congress and will be shared with regulatory authorities.

Tulisokibart has the broadest development program in the novel anti-TL1A class and is currently being evaluated in seven disease indications. Phase 3 studies include **ATLAS-UC** (**NCT06052059**) in UC and **ARES-CD** (**NCT06430801**) in Crohn's disease (CD). Phase 2 studies are evaluating tulisokibart in systemic sclerosis-associated interstitial lung disease (SSc-ILD) (**NCT05270668**), rheumatoid arthritis (RA) (**NCT07176390**), psoriatic arthritis (PsA) (**NCT07486960**), radiographic axial spondyloarthritis (r-axSpA) (**NCT07133633**) and hidradenitis suppurativa (HS) (**NCT06956235**). For an overview of Merck's clinical development program in immunology, please click **here**.

About ATLAS-UC

ATLAS-UC (**NCT06052059**) is a Phase 3, randomized, double-blind, placebo-controlled program designed to evaluate the efficacy and safety of tulisokibart in adults with moderately to severely active ulcerative colitis (UC). The program consists of two independent studies: Study 1, which includes both induction and maintenance treatment, and Study 2, which includes only induction treatment.

Study 2 is investigating whether at least one tulisokibart dose level is superior to placebo in the proportion of participants achieving clinical remission, according to the MMS at week 12. Participants were randomized to either receive a high dose IV of tulisokibart, a low dose IV of tulisokibart or an IV placebo. Key secondary endpoints at week 12 include percentage of patients who experienced endoscopic improvement, percentage of patients who achieved clinical response per MMS and percentage of patients who demonstrated histologic-endoscopic mucosal improvement.

About Ulcerative Colitis

Ulcerative colitis (UC) is one of the most common types of IBD and is a chronic progressive immuno-fibrotic disease that affects the large intestine and rectum. Recent evidence suggests that UC involves not only the mucosa but also deeper transmural changes with fibrosis in the colorectal wall**.** Millions of people worldwide live with UC, and symptoms can be unpredictable and may significantly impact quality of life. UC often follows a relapsing and remitting course, with symptoms that may include diarrhea, rectal bleeding, abdominal pain, bowel urgency and weight loss. Many patients with UC do not achieve adequate disease control despite the availability of currently approved treatments.

About Tulisokibart

Tulisokibart is an investigational humanized monoclonal antibody directed to a novel target, TL1A, that is associated with both intestinal inflammation and fibrosis (immuno-fibrosis). Tulisokibart is thought to bind both soluble and

membrane-bound TL1A. Merck is developing tulisokibart for the treatment of immune-mediated inflammatory diseases, including UC, CD, SSc-ILD, RA, PsA, r-axSpA and HS.

About Immuno-fibrosis

Immuno-fibrosis is the process by which inflammation and fibroblast activation drive disease activity and progression in many autoimmune conditions, including UC. Immuno-fibrotic diseases are chronic progressive conditions marked by immune dysregulation, inflammation and fibroblast activation. The impact of immuno-fibrosis may vary by disease, stage and patient. The complexity of immuno-fibrosis underscores the need for treatment options that address both inflammation and fibrosis. Merck is advancing research to deepen the understanding of immuno-fibrosis and help translate the science into new approaches.

Merck's Commitment to Immunology

Advances in our understanding of human biology have led to the emergence of innovative medicines and new modalities that aim to change approaches to the treatment of immune-mediated inflammatory diseases. Merck scientists are leveraging deep expertise in immunology to discover and develop therapies to help people living with these conditions. Our research is focused on investigating novel targets such as TL1A and CD30L, as well as newer modalities like T-cell engagers, and exploring their potential across a range of immune-mediated inflammatory diseases.

About Merck

At Merck, known as MSD outside of the United States and Canada, we are unified around our purpose: We use the power of leading-edge science to save and improve lives around the world. For more than 130 years, we have brought hope to humanity through the development of important medicines and vaccines. We aspire to be the premier research-intensive biopharmaceutical company in the world – and today, we are at the forefront of research to deliver innovative health solutions that advance the prevention and treatment of diseases in people and animals. We foster a diverse and inclusive global workforce and operate responsibly every day to enable a safe, sustainable and healthy future for all people and communities. For more information, visit **www.merck.com** and connect with us on **X (formerly Twitter)**, **Facebook**, **Instagram**, **YouTube** and **LinkedIn**.

Forward-Looking Statement of Merck & Co., Inc., Rahway, N.J., USA

This news release of Merck & Co., Inc., Rahway, N.J., USA (the "company") includes "forward-looking statements" within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. These statements are based upon the current beliefs and expectations of the company's management and are subject to significant risks and uncertainties. There can be no guarantees with respect to pipeline candidates that the candidates will receive the necessary regulatory approvals or that they will prove to be commercially successful. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially

from those set forth in the forward-looking statements.

Risks and uncertainties include but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; the company's ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of the company's patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

The company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in the company's Annual Report on Form 10-K for the year ended December 31, 2025 and the company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site (**www.sec.gov**).

Media Contacts:
Julie Cunningham
julie.cunningham@merck.com

Jalisa Stanislaus
jalisa.stanislaus@merck.com

Investor Contacts:
Peter Dannenbaum
(732) 594-1579

Ayn Wisler
(732) 594-0482

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